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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/930,125

08/14/2001

Susan Hand-Zimmermann

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03/09/2007

SEED INTELLECTUAL PROPERTY LAW GROUP PLLC

701 FIFTH AVE

SUITE 5400

SEATTLE, WA 98104

EXAMINER

UNGAR, SUSAN NMN

ART UNIT

PAPER NUMBER

1642

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

03/09/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/930,125	<b>Applicant(s)</b> HAND-ZIMMERMANN ET AL.	
	<b>Examiner</b> Susan Ungar	<b>Art Unit</b> 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on 03 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☐ Claim(s) 14-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 15 is/are allowed.
- 6) ☐ Claim(s) 14 and 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 31, 2006 is acknowledged and has been entered. Claims 14 has been amended. Claims 14-16 are pending and under consideration. An action on the RCE follows.

***New Grounds of Objection***

2. The specification is objected to because there appears to be an inadvertent typographical error. The specification teaches that SEQ ID NO: 3 sets forth the amino acid sequence for a naturally processed HLA-B44-restricted epitope of Her-2/neu, corresponding to amino acids 1021-1030 of the Her-2/neu protein (para 0036 of the published application), the specification also teaches that SEQ ID NO:3 consists of amino acid residues EEYLVPQQGF (para 298 of the published application (para 0036 of the published application). A review of the sequence listing submitted as originally filed, reveals that amino acid residues EEYLVPQQGF are in fact amino acid residues 1005-1014 of SEQ ID NO:2 and not amino acid residues 1021-1030. Appropriate correction is required.

***New Grounds of Rejection***

***Claim Rejections - 35 USC 112***

3. Claims 14 is rejected under 35 USC 112, first paragraph, first paragraph.

Claim 14 is rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention. The limitation of a fragment of (a) wherein said fragment is at least 100 amino acids in length and

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comprises residues 1021-1030 of SEQ ID NO2 has no clear support in the specification and the claims as originally filed. In the RCE filing of January 3, 2007, Applicant states that no new matter has been added and points to support in the specification at page 13, lines 20-24 for the newly added limitation. A review of the specification at page 13, lines 20-24 reveals support for "The present invention, in another aspect, provides polypeptide fragments comprising at least about 5, 10, 15, 20, 25, 50, or 100 contiguous amino acids, or more, including all intermediate lengths, of a polypeptide compositions set forth herein, such as those set forth in SEQ ID NOs:2-3, 8-11, and 14-15 or those encoded by a polynucleotide". However, although there is indeed support for a fragment of at least 100 amino acids in length and there is support for said fragment comprising SEQ ID NO:3, there is no support for said fragment comprising amino acid residues 1021-1030. Although the specification teaches that the fragment, amino acid residues 1021-1030, is a naturally processed HLA-B44-restricted epitope of Her-2/neu, and that those residues are disclosed in SEQ ID NO:3, the specification also teaches that SEQ ID NO:3 consists of amino acid residues EEYLVPPQGF (para 298 of the published application (para 0036 of the published application)). A review of the sequence listing submitted as originally filed, reveals that amino acid residues EEYLVPPQGF are in fact amino acid residues 1005-1014 of SEQ ID NO:2 and not amino acid residues 1021-1030. Thus, the amendment of claim 14 to recite a fragment of (a) wherein said fragment is at least 100 amino acids in length and comprises residues 1021-2030 of SEQ ID NO2 constitutes new matter.

The subject matter claimed in claim 14 broadens the scope of the invention as originally disclosed in the specification.

4. Claim 16 is rejected under 35 USC 112, first paragraph as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, essentially for the reasons previously set forth in the paper mailed January 31, 2006, Section 5, pages 3-9.

The claim is drawn to an isolated polypeptide consisting of residues 1021-1030 of SEQ ID NO:2.

The specification teaches that amino acid residues EEYLVPQQGF represent a naturally processed HLA-B44-restricted epitope of Her-2/neu and that these residues are residues 1005-1014 of SEQ ID NO:2 (see para 298 of the published application and the original sequence listing, SEQ ID NO:2). The specification also teaches that SEQ ID NO: 3 sets forth the amino acid sequence for a naturally processed HLA-B44-restricted epitope of Her-2/neu, corresponding to amino acids 1021-1030 of the Her-2/neu protein (para 0036 of the published application).

One cannot extrapolate the teaching of the specification to the enablement of the claims because it is clear that an inadvertent typographical error has occurred in the specification as originally filed because a review of the submitted sequence reveals quite clearly that amino acid residues 1021-1030 do not have the sequence identified as SEQ ID NO:3. Other than the inadvertent typographical error, there is no teaching drawn to amino acid residues 1021-1030, and one could not predict with a reasonable expectation of success that amino acid residues 1021-1030 are a naturally processed HLA-B44-restricted epitope of Her-2/neu. Further, given that there is no information in the specification, one could not predict how to use the claimed peptide of Claim 16. Although Applicant might suggest that the peptide



might be useful for producing antibodies or stimulating T cells that bind to SEQ ID NO:2, as previously set forth, in the Final Rejection mailed January 31, 2006, section 5, pages 3-9, the use of linear peptides is not predictable.

The specification provides insufficient guidance with regard to these issues drawn to claim 16 and provides no working examples which would provide guidance to one skilled in the art and no evidence has been provided which would allow one of skill in the art to predict how to use the claimed peptide with a reasonable expectation of success. For the above reasons, it appears that undue experimentation would be required to practice the claimed invention.

5. Claim 15 is allowable and free of the art.
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

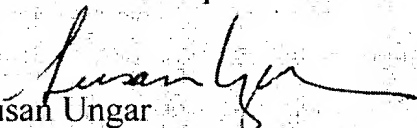
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley, can be reached at 571-272-0898. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

  
Susan Ungar  
Primary Patent Examiner  
March 2, 2007